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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,762	04/09/2001	Daniela Tornese Buonamassa	CHIR-0311	7831

7590

07/06/2005

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EXAMINER
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SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/762,762

Applicant(s)

BUONAMASSA ET AL.

Examiner

A R. Salimi

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 2-9 and 15-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10-14, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/10/02, 10/21/02</u> | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 1-51 are pending.

Submitted Information Disclosure Statement (I.D.S) is noted.

#### ***Election/Restrictions***

Applicant's election without traverse of Group II (Claims 1, 10-14, and 50-51) in the reply filed on 6/10/2005 is acknowledged.

Claims 2-9, 15-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups.

**Applicants are reminded to cancel the claims to the non-elected Group(s).**

#### ***Claim Rejections - 35 USC § 112***

Claims 10-14, and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite; the claim is directed to a "composition comprising" which means there is more than one element present. The claim has defined only one element, and the other elements that form a composition is/are missing. This affects the dependent claims.

Claim 50 is vague and indefinite; the claim is directed to a "composition comprising" which means there is more than one element present. The claim has defined only one element, and the other elements that form a composition is/are missing.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10-12, 50, and 51 rejected under 35 U.S.C. 102(b) as being anticipated by Sasagawa et al (Virology, 1995, Vol. 206, pages 126-135).

The product that is being claimed is taught by the above-cited reference, where Sasagawa et al taught expression of both capsid proteins of two different types of human papillomavirus (HPV) namely HPV-16, and HPV-6 in yeast (see the abstract, and Table 1). The claiming of a new use, i.e., induction of immune response, which is inherently present in the prior art, does not necessarily make the claim patentable. *In re Best*, 562 F.2d1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Applicants are reminded that the intended use of a product does not carry patentable weight. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1, 10-12, 50, and 51 rejected under 35 U.S.C. 102(b) as being anticipated by Buonamassa et al (Virus Research, February, 1997, Vol. 47(2): 126).

Buonamassa et al taught expression of HPV-16, and HPV-6 in yeast and taught induction of immune response in mice (see the abstract).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 10-14, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasagawa et al (Virology, 1995, Vo. 206, pages 126-135), and Ott et al, (Vaccine Design, 1995, pages 277-296).

As stated above Sasagawa et al taught a composition comprising of virus like particles (VLP) with at least two types of viruses, namely HPV-6 and HPV-16 (see the abstract). This differs since they did not add a well known adjuvant to their composition.

Ott et al taught adjuvant design to be utilized in vaccines. Additionally, they taught employment of MF59 adjuvant along with various human virus antigens including papillomavirus, wherein the efficacious results were observed (see page 282, 1<sup>st</sup> full paragraph, and Figure 4).

Therefore, one of ordinary skill in the art at the time of filing would have been highly motivated to mix the product taught by Sasagawa et al with adjuvant taught by Ott et al to obtain enhanced immune response. One of ordinary skill in the art being familiar with the above state of the would not have anticipated any unexpected results. Thus, the claimed invention as a whole is prima facie obvious absent unexpected results.

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Claims 1, 10-14, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buonamassa et al (Virus Research, February, 1997, Vol. 47(2): 126), and Ott et al, (Vaccine Design, 1995, pages 277-296).

As stated above Buonamassa et al taught a composition comprising of virus like particles (VLP) with at least two types of viruses, namely HPV-6 and HPV-16 (see the abstract). This differs since they did not add a well-known adjuvant to their composition.

Ott et al taught adjuvant design to be utilized in vaccines. Additionally, they taught employment of MF59 adjuvant along with various human virus antigens including papillomavirus, wherein the efficacious results were observed (see page 282, 1<sup>st</sup> full paragraph, and Figure 4).

Therefore, one of ordinary skill in the art at the time of filing would have been highly motivated to mix the product taught by Buonamassa et al with adjuvant taught by Ott et al to obtain enhanced immune response. One of ordinary skill in the art being familiar with the above state of the would not have anticipated any unexpected results. Thus, the claimed invention as a whole is prima facie obvious absent unexpected results.

No claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

6/28/2005

ALL R. SALIMI  
PRIMARY EXAMINER